

Serial No. 10/086,068

Patent  
018484-002121US**REMARKS**

Claims 1-157 are pending in the application. Claims 1-142 have been withdrawn from further consideration as being directed to non-elected invention..

**Specification**

The Examiner indicates that two (2) specifications and amendments to specification have been filed in the application. The Examiner has requested clarification on its history. In response, Applicants submit that the second specification has been submitted on August 5, 2002 as a substitute specification in response to the Notice to File Corrected Application Papers dated May 3, 2002 indicating that the papers filed on February 26, 2002 contain improper margins. Accordingly, the August 5, 2002 specification is to be considered on the merits together with claims 1-157. All subsequent filings amending the specification and so forth should be based on the August 5, 2002 application.

**Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 143-157 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description and enablement requirements. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

The Examiner states that the specification does not enable claims directed to a method of inhibiting an IL-1-induced biological response in a mammal, the method comprising administering to said mammal a polynucleotide encoding a cytokine which inhibits an IL-1-induced biological response, thereby systemically delivering the cytokine and inhibiting the IL-1 induced biological response as in the claims.

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Applicants submit that in one aspect, the invention is directed to suppressing the biological effects of IL-1. Applicants submit that it would not require undue experimentation to determine nucleotides that would counter the negative effects of IL-1 as an assay for carrying out such determination is fully described in the specification. Therefore, any cytokine having the indicated activity that counters the biological activity of IL-1 may be used. Moreover, a biologically active fragment of IL-10 is fully enabled by the specification and the state of the art. It would not require undue experimentation to obtain fragments of any cytokine such as IL-10. A fragment of a gene or protein has a definite size and sequence and is limited by a finite number of molecular species. Therefore, Applicants submit that the specification and the state of the art fully support claims directed to a biologically active fragment of the cytokine.

The Examiner also rejects the claims for reading on gene therapy. Applicants submit that the specification fully supports administering the polynucleotide into the site of interest in a mammal. The specification provides evidence in the Examples section that shows that the cytokine is expressed in the cells when the genes are administered to the mammal. Therefore, the Examiner's concerns have been adequately addressed.

### **Conclusion**

It is believed that the application is now in condition for allowance. Applicant requests the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR §§1.16 and 1.17 that are not covered, in whole or in part, by a

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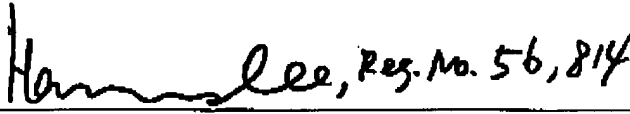
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credit card payment enclosed herewith and to credit any overpayment to said Deposit Account No. 502486.

Date: December 6, 2005

Respectfully submitted,

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